510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

Name: HET Systems, LLC
Contact: Howard Schrayer
Regulatory Affairs Consultant

Address: 200 Middlesex Turnpike – Suite 304
Iselin, NJ 08830

Telephone: (609) 924 - 9510
Fax: (732) 683 - 9476

Date Prepared April 29, 2014

General Device Information

Product Name: HET™ Bipolar Electrocautery Forceps and Monitor

Classification: "Electrosurgical cutting and coagulation device and accessories", Product code: GEI - Class II

Predicate Device

HET Systems, LLC – HET™ Bipolar Electrocautery Forceps and Monitor - 510(k) Number K121085

Description

The HET™ Bipolar Forceps is a sterile, single-use bipolar forceps having a tapered tubular configuration. The device is connected via an integrated bipolar cable to the bipolar output of an electrosurgical generator.

The accessory monitor provides power for a temperature sensor and an LED light source mounted on the disposable forceps. The HET Systems HET™ Bipolar Electrocautery Forceps and Monitor may be used with any Bipolar Electrosurgical generator in the coagulation mode with an output power set at 10 W and a maximum voltage of 1250v.

The monitor displays the temperature at the forceps-tissue interface. The HET" Monitor does not generate RF energy.

Intended Use (Indications)

The HET™ Bipolar Electrocautery Forceps and Monitor is intended to be used for grasping, manipulating and coagulating soft tissue during general surgery.

The HET™ Bipolar Electrocautery Forceps and Monitor may be used for the treatment of symptomatic Grade I and Grade II internal hemorrhoids.

Substantial Equivalence

This submission supports the position that the HET™ Bipolar Electrocautery Forceps and Monitor is substantially equivalent to a previously cleared device, specifically, the HET Bipolar Electrocautery Forceps and Monitor (K121085).

The technological characteristics of the device are unchanged (exactly the same as) the characteristics of the predicate HET Systems device that was cleared under 510(k) K121085. The purpose of this submission is to demonstrate that the HET Bipolar Electrocautery Forceps and Monitor may be used with any bipolar electrosurgical generator that can be operated at 10W output power and a maximum voltage of 1250. The materials, software, and treatment mechanism (i.e., bipolar energy used to produce heat) are unchanged. Both the predicate system and the subject device use thermal energy to achieve the treatment effect (tissue coagulation). The predicate device is indicated for the treatment of internal hemorrhoids.

The 510(k) Notice contains reports of a series of studies (in an *ex vivo* tissue model model) that were conducted to evaluate the performance and thermal effects of the device as compared to the predicate device.

Biocompatibility studies, software validations, and electrical safety studies were conducted and reported in the 510(k) Notice for the predicate HET Systems device. Because the two devices are the same, the information reported for the predicate HET device is applicable.

Performance Testing

Testing was conducted to characterize the device's performance when used in conjunction with eight FDA cleared, commercially available, bipolar electrosurgical generators. The studies evaluated to zone of thermal injury and confirmed that the treatment time was acceptable to allow safe treatment.

Biocompatibility Testing

Testing was previously conducted, and reported in the 510(k) Notice for the predicate, to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-irradiation sterilized device and in accordance with the GLP requirements: cytotoxicity, intracutaneous irritation, sensitization, acute systemic toxicity and hemocompatibility.

Clinical Testing

The 510(k) Notice for the predicate also contains reports of human clinical evaluations that were conducted to evaluate the clinical performance of the device. These studies demonstrated outcomes substantially equivalent to clinical outcomes reported in the literature for an additional predicate device.

Conclusions

HET Systems, LLC believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the indications for the HET™ Bipolar Electrocautery Forceps and Monitor. The materials from which the HET Systems device is fabricated have an established history of use in medical applications; and devices produced by HET Systems have been tested in accordance with applicable guidelines and standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 5, 2014

HET Systems, LLC
% Mr. Howard L. Schrayer
Regulatory Affairs Consultant
200 Middlesex Turnpike, Suite 304
Iselin, New Jersey 08830

Re: K140422
Trade/Device Name: HET™ Bipolar Electrocautery Forceps and Monitor
Regulation Number: 21 CFR 878.4000
Regulation Name: Electrosurgical, cutting & coagulation device & accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 30, 2014
Received: May 1, 2014

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K140422

INDICATIONS FOR USE

510(k) Number (if known): K140422

Device Name: HET™ Bipolar Electrocautery Forceps and Monitor

Indications For Use:

The HET™ Bipolar Electrocautery Forceps and Monitor is intended to be used for grasping, manipulating and coagulating soft tissue during general surgery.

The HET™ Bipolar Electrocautery Forceps and Monitor may be used for the treatment of symptomatic Grade I and Grade II internal hemorrhoids.

Prescription Use ____X_____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ian P. Broverman -S

Digitally signed by Ian P. Broverman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000792945, cn=Ian P. Broverman -S
Date: 2014.06.04 15:38:11 -04'00'